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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/110,376 05/12/98 COHEN

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| EXAMINER |
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CANELLA, K

| ART UNIT | PAPER NUMBER |
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1642

DATE MAILED:

08/30/00

HM12/0830
THE LAW OFFICE OF JAMES C SIMMONS
11 FALMOUTH LANE
WILLIAMSVILLE NY 14221

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/110,376

Applicant(s)

Cohen et al

Examiner

Karen Can Ila

Group Art Unit

1642



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1 _____ is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1 _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

1. Please note that the examiner assigned to your application in the PTO has changed.

Response to Amendment

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claim 1 is amended and under consideration.

New Claim Rejections

4. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. Claim 1 recites "high percentage of the tumor cells". One cannot determine the exact metes and bound of what the applicant considers to be a high percentage, therefore the claim is vague and indefinite.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a solid non-lymphoid primary tumor cell without tumor infiltrating lymphocytes, does not reasonably provide enablement for a solid non-lymphoid primary tumor cell with tumor infiltrating lymphocytes. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to the invention commensurate in scope with these claims. Claim 1 is drawn to a method of correlating gene expression of T-cell antigens in a solid, non-lymphoid tumor to metastatic potential of said tumor. As such, the claim does not exclude solid, non-lymphoid primary tumors which contain tumor infiltrating lymphocytes, said lymphocytes expressing the T-cell receptors beta and zeta as well as CD-3, 4 and 8 (Paul, Fundamental Immunology textbook, pg. 976-977). Tumor infiltrating lymphocytes

are usually indicative of a positive immune response of the host against the tumor, and do not correlate with increased metastatic potential. One of skill in the art would not know how to use the instant invention to predict the metastatic potential of the primary tumor in the presence of tumor infiltrating lymphocytes.

7. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kim et al (Proceeding of the American Association for Cancer Research, 1988, Vol. 29, p. 67) in view of Barbera-Guillem (USP 5,536,642). Claim 1 is drawn to a method of correlating gene expression of T-cell antigens in a solid, non-lymphoid tumor to metastatic potential of said tumor. Kim et al teach the manifestation of lymphocytic metastatic potential is correlated to expression of T-lymphocyte antigens on rat mammary carcinoma cells fused with syngeneic thymocytes. Kim does not specifically teach T-cell receptor beta. Barbera-Guillem teaches that T-cell receptor beta is expressed on non-lymphoid tumors, and the decreased expression of T-cell receptor beta on said tumor is indicative of a positive response after anti-cancer therapy. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to correlate the expression of T-cell beta antigen on non-lymphocytic tumors with metastatic potential. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Kim et al on the increased metastatic potential of rat mammary carcinoma cells when expressing T-cell antigens.

8. All other rejections cited in Paper No.10 are withdrawn.

9. All objections to the Specification cited in Paper No. 10 are maintained.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may

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Art Unit: 1642


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be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

August 27, 2000


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600